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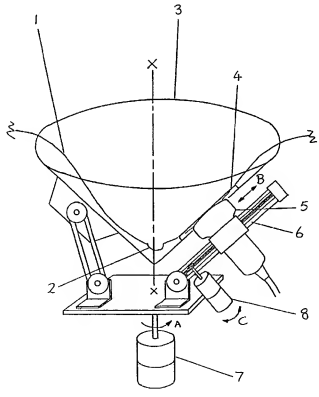
(54) Title: ULTRASONIC IMAGING DEVICE



(57) Abstract: A device for use in the imaging of breast tissue comprises: a mounting structure capable of holding an ultrasound transducer having an effective transmission face; and a tissue moulding element for receiving and surrounding the breast tissue, the mounting structure being movable relative to the surface of the breast tissue placed into the tissue moulding element, the mounting structure and tissue moulding element being arranged relative to each other such that the effective transmission face of an ultrasound transducer held by the mounting structure is maintained in an ultrasound coupled orientation with the surface of the breast tissue and substantially parallel to the surface of the breast tissue in registration with the effective transmission face during the relative movement.

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Imaging Device

This invention relates to a device for use in the imaging of biological structures and in particular to a device suitable for facilitating the carrying out of ultrasound scans, especially ultrasound scans of breast tissue.

Ultrasound imaging of biological tissue is widely applicable in medical diagnostics. Both two-dimensional and three-dimensional images can be produced, although the latter are potentially more useful. In a conventional real-time ultrasound B-scan ('brightness' scan), an array of transducers sends out ultrasonic pulses and the time of flight for the pulse-echo to return from the anatomical tissue is measured. This provides tomographic data in two dimensions. Images can also be created from Doppler ultrasound information in a comparable way. To create a three-dimensional visualisation of a tissue structure, ultrasound data must be obtained in three dimensions.

Ultrasound imaging has found particular usefulness in the field of breast cancer diagnosis. Whilst magnetic resonance imaging undoubtedly can generate images of very high diagnostic quality, costs militate against its wide use, especially for screening. In this context, ultrasound breast imaging is becoming increasingly used as a safe modality. The breast presents an apparently ideal organ for ultrasound imaging, being superficial, and without bone or gas. Indeed, approximately 5% of cancers exhibit secondary foci which will only be detected by ultrasound examination. Nevertheless, ultrasound breast scans are amongst the most difficult to interpret. This is largely because of the refraction and attenuation effects that occur in superficial tissues with a large fat component. These effects are particularly troublesome when extending from two-dimensional to three-dimensional imaging.

Ultrasound breast imaging is already an essential modality in the work-up of patients with breast disorders. In the young patient it is used in place of X-ray mammography and, for patients who have mammographic abnormalities, it is used to differentiate solid from cystic lesions and to guide needle biopsy where clinically indicated. It is also used to differentiate benign from malignant tumours. However in spite of its acknowledged equivalence to

mammography for the detection of breast cancer it is not used as a population screening tool because of the length of time taken for a thorough examination. Effective whole population screening is only feasible if the test can be performed in a few minutes, the 15 to 20 or so minutes per breast of skilled operator time required for conventional ultrasound is far too long.

One of a variety of obstacles to developing a device capable of facilitating scanning of the whole breast volume in minutes is the difficulty of maintaining good contact between the ultrasound transducer and the skin and the image quality that results from a controlled but inflexible scanning mechanism. By contrast, the conventional operator makes continual small adjustments to the probe angle to compensate for slight alterations in local attenuation levels; it is very difficult to develop a mechanically-controlled, automatic or semi-automatic scanner to mimic this action.

WO83/02053 describes an apparatus for ultrasonic examination of deformable objects such as breasts. The apparatus comprises a plate upon which the breast may be supported and an ultrasonic transducer beneath the plate. Transducers may also be included in the form of lateral compression plates. This apparatus does not provide, however, for uniform scanning of the whole breast, particularly the nipple area, and would appear to result in deformation of the tissue into non-anatomical shapes, which would tend to lead to difficulties in ensuring reproducibility between successive scans of a given patient and disguise distortions due to lesions.

In GB2015732A, a rotating ultrasonic echoscopy scanner is described which consists of a transducer mounted on a frame which allows movement of the transducer horizontally, vertically and so as to describe a substantially horizontal circle. The frame is set up in a water tank into which the patent's breast is depended so as to be directly above the transducer. A similar arrangement is shown in US4509368.

US4130112 shows an apparatus comprising a vacuum cavity for receiving the breast and having liquid-containing coupling tanks either side of the cavity. Transducers at the ends

of the coupling tanks transmit or receive ultrasound through the coupling tanks and the breast tissue.

US4075883 describes an ultrasonic scanner assembly which comprises a transmitter and an arcuate array of receivers placed at either end of a liquid-filled tank. The breast of the patient is depended into the liquid-filled tank and the tank may be rotated about the breast and moved vertically relative to the breast.

In DE3136037A, a water-filled chamber for ultrasound breast scanning is disclosed and which has a circular port covered with a soft foil into which the breast is positioned. The ultrasound transducers scan the breast across the water-filled chamber.

US4206763 concerns an apparatus for breast ultrasound imaging and which uses a compartment into which water is drawn, by suction, over the breast and in which a transducer revolves around the breast to obtain 360 degree, two-dimensional scans.

The prior art does not provide, however, any apparatus having utility in the ultrasound scanning of breast tissue and which is simple and rapid to use, fairly portable, and capable of reproducible measurement of the entire breast and which maintains the ultrasound transducer or transducers in an optimal or near-optimal position relative to the tissue for the majority of the scan. The prior art devices are generally bulky and consist of a large number of complex interrelated components. Furthermore, those devices which employ liquid-filled coupling chambers suffer from the problem that the transducer is inevitably sited further away from the tissue and hence the focus of the ultrasound beam is poorer. This reduces lateral resolution. These systems also suffer from reverberant echoes arising from the multiple interfaces through which the ultrasound must travel, these echoes leading to artefacts in the resulting images.

Thus, it is an object of the present invention to provide a device which at least partially overcomes the problems identified above in relation to the prior art.

Accordingly, one aspect of the present invention provides a device for use in the imaging of breast tissue, the device comprising: a mounting structure capable of holding an ultrasound transducer having an effective transmission face; and a tissue moulding element for receiving and surrounding the breast tissue, the mounting structure being movable relative to the surface of the breast tissue placed into the tissue moulding element, the mounting structure and tissue moulding element being arranged relative to each other such that the effective transmission face of an ultrasound transducer held by the mounting structure is maintained in an ultrasound coupled orientation with the surface of the breast tissue and substantially parallel to the surface of the breast tissue in registration with the effective transmission face during the relative movement.

As used herein, the term 'ultrasound coupled orientation' implies physical contact between the effective transmission face and the surface of the tissue, or contact through interposing thin solid or liquid layers but not through an interposing gas or air layer. The term 'effective transmission face' refers to that part of an ultrasound transducer from which ultrasound energy ultimately emanates to be transferred into the tissue or a thin interposing solid or liquid layer.

Preferably, the tissue moulding element of the device of the present invention has a substantially circular or elliptical cross section. More preferably, the tissue moulding element has a substantially circular cross section. Most preferably, the tissue moulding element has a three-dimensional shape which is approximately conical, domed or an ellipsoidal segment, or a truncated or skewed form of a cone, dome or ellipsoidal segment. The tissue moulding element may comprise a plurality of sections which co-operate to receive and surround the breast tissue. In an advantageous embodiment, the tissue moulding element has the three dimensional shape of a right circular cone. It will be appreciated that, despite the advantages inherent in using geometric and well-defined shapes of tissue moulding element, the invention may also be carried out using bespoke tissue moulding elements to ensure as close as possible conformity with breast shapes of all varieties.

In the device of the present invention, the relative movement of the mounting structure may take place in two dimensions over the three dimensional surface of the breast tissue placed into the tissue moulding element. The relative movement of the mounting structure is preferably effected by drive means. It is preferred that the position on the mounting structure at which the transducer is held is adjustable so as to allow the transmission face to be moved in two dimensions over the three dimensional surface of the breast tissue placed into the tissue moulding element. Such additional movements or adjustments facilitate the acquisition of three-dimensional scan data.

The relative arrangement of the mounting structure and tissue moulding element may be maintained by electronically programming a controllable element of the drive means for the movement of the mounting structure with information relating to the shape of the tissue moulding element. The relative arrangement of the mounting structure and tissue moulding element may alternatively or in addition be maintained by providing the drive means with one or more sets of cams and cam followers whose shapes correspond with the shape of the tissue moulding element, and/or by the provision of a feedback loop which responds to the shape of the tissue moulding element by moving the mounting structure towards or away from the tissue moulding element so as to maintain the effective transmission face of the transducer in the ultrasound coupled and substantially parallel orientation with the surface of the breast tissue. The feedback loop may be electronically controlled.

In a preferred embodiment of the device of the present invention, the mounting structure is rotatable so as to follow a perimeter of the tissue moulding element. In those embodiments employing a tissue moulding element with a substantially circular cross section, the relative movability of the mounting structure is particularly simplified since it involves merely the rotation of that structure so as to follow a circumference of the tissue moulding element. In embodiments employing tissue moulding elements with other cross sectional characteristics, the movement of the mounting structure may involve both rotation and a degree of radial movement so as to follow, as closely as possible, a perimeter of the tissue moulding element. A window may be provided in the tissue moulding element through which ultrasound may be transmitted, in use, by a transducer held by the mounting

structure, the tissue moulding element being movable, in use, with the mounting structure so as to keep the transducer and the window in registration. The window may be covered with a thin, ultrasound permeable membrane.

In certain embodiments a negative pressure may be applied to the tissue moulding element so as to enhance the moulding of the breast tissue placed therein.

The device of the present invention preferably has an ultrasound transducer held on the mounting structure. The transducer is preferably suitable for carrying out pulse-echo or Doppler ultrasound imaging.

In another aspect of the present invention, there is provided a method for the imaging of breast tissue, the method comprising the steps of:

i) providing a device comprising: a mounting structure holding an ultrasound transducer having an effective transmission face; and a tissue moulding element for receiving and surrounding the breast tissue, the mounting structure being movable relative to the surface of the breast tissue placed into the tissue moulding element, the mounting structure and tissue moulding element being arranged relative to each other such that the effective transmission face of the ultrasound transducer is maintained in an ultrasound coupled orientation with the surface of the breast tissue and substantially parallel to the surface of the breast tissue in registration with the effective transmission face during the relative movement;

ii) placing the breast tissue to be imaged into the tissue moulding element;

iii) causing the mounting structure to undergo the relative movement; and

iv) imaging the breast tissue coupled to the effective transmission face of the ultrasound transducer.

In preferred embodiments of the method of the present invention, the tissue moulding element has a substantially circular or elliptical cross-section. In more preferred embodiments, the tissue moulding element has a substantially circular cross-section; such a cross-section simplifies the relative movement.

The method may include the additional step of reconstructing a three-dimensional image from multiple two-dimensional images taken at known positions and orientations.

It is preferred that a coupling medium is used between the effective transmission face and the tissue moulding element and/or between the tissue moulding element and the surface of the breast tissue placed therein. The coupling medium enhances acoustic coupling and provides lubrication. A suitable oil or gel, or alcohol solution or water may be used as the coupling medium. When the tissue moulding element is fitted with a window as described above, the transmission face may make contact with the breast tissue surface. A coupling medium is preferably interposed between the effective transmission face and the breast tissue surface in this case or, when the window is covered with a membrane as described above, the coupling medium is preferably interposed between the effective transmission face and the membrane and/or the membrane and the breast tissue surface. The lubricating properties of the coupling medium are especially important in those embodiments of the present invention in which the tissue moulding element is intended to be moved with the mounting structure, the tissue moulding element then being required, typically, to rotate about the breast-tissue.

In a further aspect, the present invention provides a method for the imaging of breast tissues, the method comprising the steps of:

i. placing the breast tissue to be imaged into a tissue moulding element which receives and surrounds the breast tissue;

ii. moving an ultrasound transducer relative to the surface of the breast tissue, using the tissue moulding element as a guide and such that the effective transmission face of the ultrasound transducer is maintained in an ultrasound coupled orientation with the

surface of the breast tissue and substantially parallel to the surface of the breast tissue in registration with the effective transmission face; and

imaging the breast tissue coupled to the effective transmission face of the ultrasound transducer.

The present invention allows the simple and rapid acquisition of two-dimensional or three-dimensional data by automatically scanning a single transducer or a linear, curvilinear or phased array of transducers over the tissue constrained within the tissue moulding element. To use the device of the invention for imaging different breast tissues, different shapes of tissue moulding elements may be used. The device takes advantage of the fact that the breast is approximately conical or skewed-conical in shape. The tissue moulding element is used to constrain the breast to conform to the desired conical or skewed-conical shape with minimum disturbance of the three-dimensional architecture of the breast tissue. A dome-shaped tissue moulding element, or a tissue moulding element having the shape of an ellipsoidal segment (e.g. hemi-ellipsoidal, like half a transversely-sectioned rugby ball), may also be used for breast imaging; the shape is chosen depending on the shape of the patient's breast so as to ensure the best fit of the breast within the tissue moulding element. The use of a given shape of tissue moulding element for repeated scans of a given patient enhances the ability of the clinician to detect changes in the ultrasonic profile of the breast with minimal interference from artefacts due to inconsistency of breast compression and transducer attitude between scans. The transducer is positioned as close to the breast as possible, and aligned such that the effective transmission face of the transducer is parallel to the surface of the breast tissue in registration with the effective transmission face. The transducer is typically made to rotate around the base-apex axis of the tissue moulding element. The tissue moulding element may rotate with the transducer, or may be stationary relative to the breast. The position of the transducer may be altered up or down the sloped or curved side of the tissue moulding element to obtain three-dimensional ultrasonic data for the whole breast.

By conforming the tissue to be imaged into a predetermined shape, the reconstruction of the image data by digital electronic means is made more simple and rapid. The device of the present invention not only achieves this advantage with minimum disruption of the

tissue architecture but also allows for an extremely rapid, accurate and efficient acquisition of ultrasound data by virtue of the fact that the effective transmission face of the transducer is held in an ongoing coupled orientation with the tissue and substantially parallel to the surface of the tissue (thus ensuring that the ultrasound beams are as nearly as possible normal to the surface of the tissue) during the majority of the imaging process. In preferred embodiments in which the tissue moulding element is approximately conical, ellipsoidal segment or dome shaped (or truncated forms of these shapes, such as a frusto-cone), the image data reconstruction is made even more efficient by virtue of the geometrical simplicity of these shapes. Such shapes also provide for a greater ease of movement of the mounting structure and transducer about the tissue.

Normal operation of the device of the present invention does not require the assembly of large liquid-filled baths or complex arrays of transmitters and receivers around the tissue to be imaged. This provides the further advantage that the device is relatively portable, easy to use and compatible with the existing equipment held by most clinics.

The invention will now be described in more detail by way of example only and with reference to the accompanying drawing which shows a device according to the present invention having a conical tissue moulding element and being used in the imaging of a dependent breast.

The breast is a superficial, soft, mobile organ. These characteristics impose considerable constraints on the design of an automated scanning mechanism. There are two fundamental options available for patient positioning: prone with dependent breasts; supine in a lateral decubitus position. Prone positioning has the advantage that the breast tissue falls away from the chest wall and for this reason it is the position of choice for magnetic resonance imaging. However, for ultrasound imaging, a major disadvantage is the difficult geometry that the skin surface then presents to the beam. Ultrasound is very susceptible to the physical effect of refraction. This phenomenon, which leads to image degradation, is particularly marked in situations where the beam crosses sharply curved boundaries. The dependent breast is such a situation.

In using the device of the present invention to obtain an image of breast tissue, the patient lies in a prone position such that her breast 1 hangs within the conical tissue moulding element or former 3. A conical former is chosen to be an appropriate shape and size for the patient's breast. The former 3 may be raised or lowered (or alternatively the patient may be moved up or down) to press the breast into the shape of the cone. The former 3 may also be translated in a horizontal plane (or alternatively the patient may be moved) to ensure that the nipple 2 is aligned with the apex of the cone.

A hole 4 is made in the former 3 and which may be covered by a thin membrane. A pulse-echo ultrasonic transducer 5 presses against the membrane (or the skin surface) and is positioned normal to the surface of the breast. An aqueous gel is smeared between the transducer 5 and the membrane to give improved acoustic coupling. A small amount of paraffin oil is introduced into the former 3 and which improves acoustic coupling and also provides lubrication between the breast 1 and the conical former 3.

The transducer 5 is able to move up and down a pair of slide rails 6 such that the face of the transducer moves parallel to the surface of the former 3. The whole structure, consisting of conical former 3, transducer 5 and slide rails 6 rotates about the axis X-X of the former 3.

The rotation may be powered by an electric motor 7 (as shown by arrow A). The movement of the transducer up and down the slide rails 6 (arrow B) may also be powered by an electrical actuator 8, in this embodiment by rotation of the actuator 8 in the directions indicated by arrow C, the actuator 8 having teeth which engage with corresponding teeth situated between the slide rails 6.

To acquire ultrasonic data of the whole breast volume the transducer 5 is moved to its uppermost position. The device is rotated through a complete revolution of 360 degrees plus a small angular overlap. The transducer is moved down to a position such that adjacent scans slightly overlap. The device is then rotated again through a complete revolution. This continues until the nipple region 2 of the breast has been scanned. The rotation should always be in the same direction when data is being acquired, since the breast may become slightly deformed due to the friction between breast 1 and conical

former 3. The transducer 5 may need to be reversed through a complete revolution between scans to ensure that the transducer cable does not become wound up. In an alternative embodiment, an ultrasound transducer is used which has an effective transmission face which extends along the outer wall of the tissue moulding element or former 3 from near or at its base to near or at its apex. In such an embodiment, only one (or very few) rotations of the device are required in order to acquire ultrasound data for the whole breast volume.

Claims

1. A device for use in the imaging of breast tissue, the device comprising: a mounting structure capable of holding an ultrasound transducer having an effective transmission face; and a tissue moulding element for receiving and surrounding the breast tissue, the mounting structure being movable relative to the surface of the breast tissue placed into the tissue moulding element, the mounting structure and tissue moulding element being arranged relative to each other such that the effective transmission face of an ultrasound transducer held by the mounting structure is maintained in an ultrasound coupled orientation with the surface of the breast tissue and substantially parallel to the surface of the breast tissue in registration with the effective transmission face during the relative movement.

2. A device according to claim 1 in which the tissue moulding element has a substantially circular or elliptical cross section.

3. A device according to claim 2 in which the tissue moulding element has a three dimensional shape which is approximately conical, domed or an ellipsoidal segment, or a truncated or skewed form of a cone, dome or ellipsoidal segment.

4. A device according to any of claims 1 to 3 wherein the tissue moulding element comprises a plurality of sections which co-operate to receive and surround the breast tissue.

5. A device according to any preceding claim in which the tissue moulding element has the three dimensional shape of a right circular cone.

6. A device according to any preceding claim in which the relative movement of the mounting structure takes place in two dimensions over the three-dimensional surface of the breast tissue placed into the tissue moulding element.

7. A device according to any preceding claim in which the position on the mounting structure at which the transducer is held is adjustable so as to allow the effective transmission face to be moved in two dimensions over the three-dimensional surface of the breast tissue placed into the tissue moulding element.

8. A device according to any preceding claim in which the relative movement of the mounting structure is effected by drive means.

9. A device according to claim 8 in which the relative arrangement of the mounting structure and tissue moulding element is maintained by electronically programming a controllable element of the drive means for the movement of the mounting structure with information relating to the shape of the tissue moulding element.

10. A device according to claim 8 or 9 in which the relative arrangement of the mounting structure and tissue moulding element is maintained by providing the drive means with one or more sets of cams and cam followers whose shapes correspond with the shape of the tissue moulding element.

11. A device according to any of claims 8 to 10 in which the relative arrangement of the mounting structure and tissue moulding element is maintained by the provision of a feedback loop which responds to the shape of the tissue moulding element by moving the mounting structure towards or away from the tissue moulding element so as to maintain the effective transmission face of the transducer in the ultrasound coupled and substantially parallel orientation with the surface of the breast tissue.

12. A device according to claim 11 in which the feedback loop is electronically controlled.

13. A device according to any preceding claim in which the mounting structure is rotatable so as to follow a perimeter of the tissue moulding element.

14. A device according to any of claims 1 to 12 in which a window is provided in the tissue moulding element through which ultrasound may be transmitted, in use, by a transducer held by the mounting structure, the tissue moulding element being movable, in use, with the mounting structure so as to keep the transducer and the window in registration.

15. A device according to claim 14 in which the window is covered with a thin, ultrasound permeable membrane.

16. A device according to any preceding claim in which a negative pressure may be applied to the tissue moulding element so as to enhance the moulding of the breast tissue placed therein.

17. A device according to any preceding claim having an ultrasound transducer held on the mounting structure.

18. A device according to claim 17 in which the transducer is suitable for carrying out pulse-echo or Doppler ultrasound imaging.

19. A method for the imaging of breast tissue, the method comprising the steps of:

i) providing a device comprising: a mounting structure holding an ultrasound transducer having an effective transmission face; and a tissue moulding element for receiving and surrounding the breast tissue, the mounting structure being movable relative to the surface of the breast tissue placed into the tissue moulding element, the mounting structure and tissue moulding element being arranged relative to each other such that the effective transmission face of the ultrasound transducer is maintained in an ultrasound coupled orientation with the surface of the breast tissue and substantially parallel to the surface of the breast tissue in registration with the effective transmission face during the relative movement;

ii) placing the breast tissue to be imaged into the tissue moulding element;

iii) causing the mounting structure to undergo the relative movement; and

iv) imaging the breast tissue coupled to the effective transmission face of the ultrasound transducer.

20. A method according to claim 19 in which the tissue moulding element has a substantially circular or elliptical cross-section.

21. A method according to claim 20 in which the tissue moulding element has a shape which is approximately conical, domed or an ellipsoidal segment, or a truncated or skewed form of a cone, dome or ellipsoidal segment.

22. A method according to any of claims 19 to 21 in which the position on the mounting structure at which the transducer is held is adjustable so as to allow the effective transmission face to be moved in two dimensions over the three dimensional surface of the tissue placed into the tissue moulding element.

23. A method according to claim 22 which includes the additional step of reconstructing a three-dimensional image from multiple two-dimensional images taken at known positions and orientations.

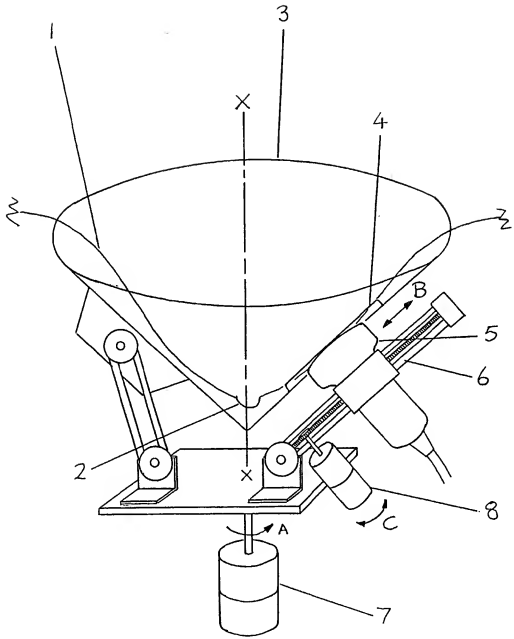
24. A method according to any of claims 19 to 23 in which the mounting structure is rotated so as to follow a perimeter of the tissue moulding element.

25. A method according to any of claims 19 to 23 in which a window is provided in the tissue moulding element through which ultrasound may be transmitted by the transducer and the tissue moulding element is moved with the mounting structure so as to keep the transducer and the window in registration.

26. A method for the imaging of breast tissues, the method comprising the steps of:
placing the breast tissue to be imaged into a tissue moulding element which receives and surrounds the breast tissue;

i. moving an ultrasound transducer relative to the surface of the breast tissue, using the tissue moulding element as a guide and such that the effective transmission face of the ultrasound transducer is maintained in an ultrasound coupled orientation with the surface of the breast tissue and substantially parallel to the surface of the breast tissue in registration with the effective transmission face; and

ii. imaging the breast tissue coupled to the effective transmission face of the ultrasound transducer.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INTERNATIONAL SEARCH REPORT

Inter ional Application No
PCT/GB 03/02386

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B8/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	US 4 130 112 A (FRAZER) 19 December 1978 (1978-12-19) cited in the application the whole document	2,3,5, 16,19-26
Y	US 4 075 883 A (GLOVER) 28 February 1978 (1978-02-28) cited in the application column 6, line 29 -column 7, line 14; figures 1-12	9

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search	Date of mailing of the international search report
18 September 2003	25/09/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Hunt, B

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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